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10/646,436

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EXAMINER

CHONG, KIMBERLY

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UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte MARTIN GLEAVE, BURKHARD JANSEN, JOANNIS P.
TROUGAKOS, EFSTATHIOS GONOS, MAXIM SIGNAEVSKY, and
ELIANA BERALDI

Appeal 2007-4460
Application 10/646,436
Technology Center 1600

Decided: April 22, 2008

Before , DEMETRA J. MILLS, ERIC GRIMES, and JEFFREY N.
FREDMAN *Administrative Patent Judges.*

GRIMES, *Administrative Patent Judge.*

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to RNA complementary to the human clusterin gene, which the Examiner has rejected as anticipated. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

BACKGROUND

“Clusterin is expressed in increased amounts by prostate tumor cells following androgen withdrawal. Furthermore, it has been determined that antisense therapy which reduces the expression of clusterin provides

therapeutic benefits in the treatment of cancer.” (Spec. 6.) “Sequences of specific RNA molecules . . . can be used alone or in combination with other chemotherapy agents or apoptosis inducing treatment concepts in the treatment of prostate cancer, sarcomas such as osteosarcoma, renal cell carcinoma, breast cancer,” etc. (*Id.*)

DISCUSSION

1. CLAIMS

Claims 1-3 and 10-13 are on appeal. Claims 4, 14, 20, 21, 23, 29, and 31-34 are also pending but are not rejected (App. Br. 1).

Claims 1-3 and 10-13 have not been argued separately and therefore stand or fall together. 37 C.F.R. § 41.37(c)(1)(vii). Claims 1 and 10 are representative and reads as follows:

1. An RNA molecule having a sequence effective to mediate degradation or block translation of mRNA that is the transcriptional product of a target gene, wherein the target gene encodes clusterin, and the RNA molecule comprises a sequence of bases complementary to the gene for human clusterin.
10. A pharmaceutical composition comprising an RNA molecule having a length of less than 49 bases and having a sequence effective to mediate degradation or block translation of mRNA that is the transcriptional product of a target gene, wherein the target gene encodes clusterin, and the RNA molecule comprises a sequence of bases complementary to the gene for human clusterin, together with a pharmaceutically acceptable carrier.

2. ANTICIPATION

Claims 1-3 and 10-13 stand rejected under 35 U.S.C. § 102(e) as anticipated by Monia.¹ Claims 10 and 11 also stand rejected under 35 U.S.C. § 102(b) as anticipated by Monia.²

The Examiner finds that

Monia et al. teach an oligonucleotide that can be RNA or a ribozyme (see column 6, lines 37-63) and that is targeted to clusterin mRNA (see Table 1). Monia et al. further teach the compounds are preferably from 12 to 30 nucleotides in length (see column 6, lines 54-59). Monia et al. teach a pharmaceutical composition comprising an RNA molecule and wherein the pharmaceutically acceptable carrier is a sterile injectable solution (see column 14, lines 4-10).

(Ans. 5.) The Examiner finds that Monia anticipates claims 1 and 10.

We agree. Monia teaches “antisense oligonucleotides, which are targeted to a nucleic acid encoding clusterin, and which modulate the expression of clusterin” (Monia, col. 3, ll. 33-35). Monia states that “the term ‘oligonucleotide’ refers to an oligomer or polymer of ribonucleic acid (RNA) or deoxyribonucleic acid (DNA) or mimetics thereof” (*id.* at col. 6, ll. 37-40). Monia discloses numerous specific oligonucleotides that inhibit clusterin expression (*id.* at cols. 42-47). The “oligonucleotides were designed to target different regions of the human clusterin RNA” (*id.* at col. 42, ll. 20-21). The exemplified oligonucleotides consisted of 2'-deoxy-

¹ Monia et al., U.S. Patent 6,383,808 B1, issued May 7, 2002 (application filed Sept. 11, 2000).

² As we understand it, the Examiner has concluded that claims 10 and 11 are not entitled to priority under 35 U.S.C. § 119(e) and therefore Monia qualifies as prior art under 35 U.S.C. § 102(b) with respect to those claims. See Office action mailed Jan. 9, 2006, page 2. The Appeal Brief and Reply Brief do not contest the denial of priority.

nucleotides and 2'-methoxyethyl nucleotides, not RNA (*id.* at col. 42, ll. 31-37).

We agree with the Examiner that Monia discloses RNA molecules that inhibit clusterin expression even though it does not exemplify them. Monia discloses that antisense oligonucleotides made of either RNA or DNA inhibit clusterin expression (i.e., they either mediate degradation or block translation of the clusterin mRNA), and exemplifies inhibition of clusterin expression using numerous specific oligonucleotides.

It is true that the exemplified antisense oligonucleotides were not made of RNA. Appellants argue that this fact shows that Monia is not enabling: “Monia does [sic, does not?] provide an enabling disclosure of any species within the scope of the invention as claimed” (App. Br. 4). “[A]ll the Monia patent provides is a generic mention of RNA molecules as an alternative to the DNA species disclosed, and an invitation to experiment to find ones that may work. There is no disclosure of even one RNA sequence, and thus the reference does not place the public in possession of any embodiment within the scope of the presently claimed invention” (*id.* at 4-5).

We agree with the Examiner that Monia’s disclosure is sufficient to put clusterin-inhibiting RNAs in the possession of those skilled in the art. “[A]nticipation does not require actual performance of suggestions in a disclosure. Rather, anticipation only requires that those suggestions be enabled to one of skill in the art.” *Impax Labs., Inc. v. Aventis Pharms. Inc.*, 468 F.3d 1366, 1382 (Fed. Cir. 2006) (quoting *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1378 (Fed. Cir. 2001)). And “[t]he

enablement requirement for prior art to anticipate under section 102 does not require utility, unlike the enablement requirement for patents under section 112.” *Id.* at 1381. Thus, the lack of actual working examples of clusterin-inhibiting RNAs does not by itself show nonenablement.

“In patent prosecution, the examiner is entitled to reject application claims as anticipated by a prior art patent without conducting an inquiry into whether or not that patent is enabled or whether or not it is the claimed material (as opposed to the unclaimed disclosures) in that patent that are at issue.” *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1355 (Fed. Cir. 2003). “[A] presumption arises that both the claimed and unclaimed disclosures in a prior art patent are enabled.” *Id.*

Monia is a prior art patent and discloses that antisense RNA molecules targeted to clusterin inhibit clusterin expression. In other words, Monia discloses that RNAs complementary to the sequence of the clusterin gene either mediate degradation or block translation of clusterin mRNA. That disclosure, which meets the limitations of instant claim 1, is entitled to a presumption of enablement. *Amgen*, 314 F.3d at 1355.

“The applicant, however, can then overcome that rejection by proving that the relevant disclosures of the prior art patent are not enabled.” *Id.* In this case, Appellants have provided no evidence to show that those skilled in the art would have had to perform undue experimentation to make an RNA within the scope of claim 1 based on Monia’s disclosure.

Appellants have not overcome the presumption of enablement to which Monia is entitled. We therefore affirm the rejection of claims 1-3 and

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10-13 under 35 U.S.C. § 102(e) and the rejection of claims 10 and 11 under 35 U.S.C. § 102(b).

No time period for taking subsequent action in connection with this appeal may be extended under 37 CFR 1.136(a).

AFFIRMED

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